MAY 3 0 2001

0002

Section II

510(k) SUMMARY

K011002

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:

Applicant Information:

Date Prepared:	March 30, 2001
Name:	Intuitive Surgical, Inc.
Address:	1340 W. Middlefield Road Mountain View, California 94043
Contact Person:	David Casal, Ph.D.
Phone Number:	(415) 237-7013
Facsimile Number:	(415) 526-2060
E-mail:	david_casal@intusurg.com

Device Information:

Classification:	Class I/II - Gynecologic Laparoscope and Accessories Electrocautery, Endoscope and Accessories
Trade Name:	Intuitive Surgical™ Endoscopic Instrument Control System and Endoscopic Instruments.
Common Name:	Endoscopic Instruments and Accessories
Classification Name:	Endoscope and Accessories (21 CFR 876.1500) Gynecologic Laparoscope and Accessories (21 CFR 884.1720)

Predicate Devices:

Substantial equivalence data for the Intuitive Surgical™ Surgical System and Endoscopic Instruments were provided in the original pre-market notifications (K002489, K990144, K965001). Data included in this submission demonstrate the safety and effectiveness of the da Vinci™ Surgical System for laparoscopic radical prostatectomy.

Device Description:

The working ends and elements of the Intuitive Surgical™ Endoscopic Instruments and Accessories are essentially identical in size and shape to the predicate devices referenced

and represent standard embodiments of standard surgical tools modified for use with the Intuitive Surgical™ Endoscopic Instrument Control System.

Intended Use:

The Intuitive Surgical® Endoscopic Instrument Control System (hereinafter referred to as the "da Vinci™ System") is intended to assist in the accurate control of Intuitive Surgical® endoscopic instruments including: rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories during laparoscopic surgical procedures such as cholecystectomy, Nissen fundoplication, radical prostatectomy, and general non-cardiac thoracoscopic surgical procedures such as internal mammary artery mobilization. It is intended to be used by trained physicians in an operating room environment.

Intuitive Surgical® Endoscopic Instruments including scissors, scalpels, forceps/pick-ups, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

Comparison to Predicate Device(s):

The Intuitive Surgical™ Instruments are essentially identical in terms of shape, size, function and tissue effect to the standard Class I and II endoscopic instruments cited.

***In Vitro* Test Data:**

Design analysis and comparison as well as *in vitro* testing confirm that basic functional characteristics are substantially equivalent to the predicate devices cited.

Summary:

Based upon the product technical information provided, intended use, and performance information provided in this pre-market notification, the Intuitive Surgical Endoscopic Instrument Control System has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2001

David Casal, Ph.D.
Vice-President, Clinical, Regulatory
and Quality Affairs
Intuitive Surgical, Inc.
1340 W. Middlefield Road
Mountain View, California 94043

Re: K011002
Trade/Device Name: Intuitive Surgical™ da Vinci™ Endoscopic Instrument Control System and Endoscopic Instruments
Regulation Number: 876.1500
Regulatory Class: II
Product Code: NAY
Dated: March 30, 2001
Received: April 3, 2001

Dear Dr. Casal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

0003

510(k) Number (if known): K011002

Device name: Intuitive Surgical™ da Vinci™ Endoscopic Instrument Control System and Endoscopic Instruments

Indications for Use:

The Intuitive Surgical® Endoscopic Instrument Control System (hereinafter referred to as the "da Vinci™ System") is intended to assist in the accurate control of Intuitive Surgical® endoscopic instruments including: rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories during laparoscopic surgical procedures such as cholecystectomy, Nissen fundoplication, radical prostatectomy, and general non-cardiac thoracoscopic surgical procedures such as internal mammary artery mobilization. It is intended to be used by trained physicians in an operating room environment.

Intuitive Surgical® Endoscopic Instruments including scissors, scalpels, forceps/pick-ups, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

PLEASE DO NOT WRITE BELOW THIS LINE
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the Counter Use_____

(per 21 CFR §801.109 (Optional Format 1-2-96)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011002